LETTER 62 - FRIENDS OF THE BITTERROOT, WOMEN'S VOICES FOR THE EARTH, COALITION FOR A SAFE LAB

Comments on the Supplemental Draft Environmental Impact Statement (SDEIS) for the Integrated Research Facility, RML

February 2004

Comments submitted with the primary purpose of facilitating the democratic process in helping Mr. Stephen A. Ficca, the Decision Maker, and Dr. Fauci, the Director of NIAID, and the public make a decision based on an open disclosure of a science based analysis of the benefit, costs and risks of the RML BSL-4 lab expansion.

Friends of the Bitterroot

WE
Women's Voices for the Earth

Friends of the Bitterroot
Women's Voices for the Earth
Coalition for a Safe Lab

February 11, 2004

To: Valerie Nottingham
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Subject: Comments and concerns regarding the Supplemental Draft Environmental Impact Statement for the National Institutes of Health, Rocky Mountain Laboratories proposed Integrated Research Facility in Hamilton, Montana

Date: February 11, 2004

Dear Ms. Nottingham,

We appreciate the opportunity to comment on the Supplemental Draft Environmental Impact Statement (SDEIS) for the National Institutes of Health (NIH) Rocky Mountain Laboratories (RML) proposed Biosafety Level-4 (BSL-4) Integrated Research Facility in Hamilton, Montana. Our members in the Bitterroot Valley and surrounding areas have demonstrated considerable interest and concern about this project which poses significant impacts to nearby communities. Our interest is to ensure that the EIS process generates meaningful discussions, disclosures and analyses between NIH, RML and the public about these impacts.

We understand that the SDEIS was released in an effort to include new and significant information and analyses not previously included in the original DEIS. We appreciate this effort, but we are disappointed that the majority of our comments on the DEIS were not addressed in this new document. Althoug somewhat improved, there continues to be a lack of meaningful discussions, disclosures and/or analysis in the SDEIS and believe that it falls short of the thoughtful, thorough analysis and study that characterizes the scientific investigations carried out by NIH. We believe the SDEIS can be significantly improved to provide the information that is needed to assess the risks and establish effective mitigation.

The duties of federal agencies under National Environmental Policy Act (NEPA) are

defined in great detail under the Council on Environmental Quality (CEQ) Regulations found at 40 C.F.R. 1500 et. Seq. The regulations are not discretionary, and apply to all agencies:

> "40 C.F.R. 1500.3 – MANDATE:
> Parts 1500 through 1508 of this title provide regulations applicable to and binding on all Federal agencies for implementing the procedural provisions of the NEPA."

The Supreme Court has instructed that the CEQ regulations are entitled to "substantial deference". (Andrus v. Sierra Club, 442 U.S. 347, 358 (1978); Accord, Robertson v. Methow Valley, 490 U.S. 332 (1989))

Additionally, a number of Circuits have held that the CEQ regulations are controlling. (See, e.g., National Indian Youth Council v. Watt, 644 F.2d 220 (10th Cir. 1981); Sierra Club v. Sigler, 695 F.2d 957 (5th Cir. 1983))

The DEIS acknowledges several times that the NEPA/CEQ regulations are controlling, (DEIS 1-1, 1-2, and 1-6). Furthermore, the DEIS states that: "This document follows the Council of Environmental Quality regulations for implementing procedural provisions of NEPA (40 CFR Parts 1500-1508)." (DEIS 1-1)

We respectfully disagree. We believe that the SDEIS contains fatal procedural flaws and does not fully and completely comply with the CEQ regulations.

The analysis presented in the SDEIS continues to be inadequate given the scope and cost of this project. The NIH has provided several opportunities for the community to ask questions and provide input in the scoping process. As a result, the NIH received hundreds of substantive comments and detailed questions on the project from a caring and interested community. The very brief resulting document does not do justice or show respect for the efforts community members have taken to comment on the project.

The SDEIS does not reflect the competency or abilities of its authors, Maxim Technologies. For example, the Voluntary Cleanup Plan, which Maxim Technologies recently authored for RML, is both longer and more thorough than the SDEIS, despite the fact that it describes a considerably smaller and less expensive project. The community has shown their sincere interest in this project and we deserve more thorough answers to our questions.

62-1 For this reason, a third draft environmental impact statement is warranted to allow for public review of the answers to the questions the public has asked.

The General Administration Manual for the Department of Health and Human Services includes a section on environmental protection outlining procedures for Environmental Impact Statements conducted by the department. Section 30-30-40 states:

"Whenever a draft environmental impact statement is significantly revised because of

Comment	Response
62-1	Please see response to comment 47-7.

comments received or because the nature or scope of the proposed action changes significantly, OPDIVs/STAFFDIVs shall prepare a new draft environmental impact statement for circulation." (Revised General Administration Manual, HHS Part 30, Environmental Protection. Published in the Federal Register: February 25, 2000 (Volume 65, Number 38) Pages 10229-10284.)

Given the continuing significant flaws in the SDEIS and outlined in our comments, your manual requires NIH and RML to significantly improve the SDEIS and republish it for public comment.

62-2 In addition, we, and the Bitterroot valley citizens whom we represent and inform, have been illegally denied important documents and information that are crucial to meaningful participation in the NEPA process for the proposed BSL-4 expansion at Rocky Mountain Laboratories (pursuant to 40 C.F.R. 1506.6 and 1507.1). The NIH is currently in violation of Freedom of Information Regulation 5.35(b)(2) for not responding to Friends of the Bitterroot's FOIA appeal, received by the FOIA appeals office November 10th, 2003, by the required deadline. The NIH has also violated 5 U.S.C. 552(a)(6)(A)(iii) and 45 C.F.R. 5.45(a)(1)(2) for not granting a fee waiver request, as required by law. The NIH has been in possession of this FOIA request for 6 months and has failed to act. We view these actions as deliberate stonewalling of our groups and the large number of citizens that we represent, while NIH hurriedly moves forward with the NEPA process on the proposal. For this reason, we require that the deadline for comments on the SDEIS be extended until 45 days after we receive the documents in our FOIA request, to which we are legally entitled.

If you have any questions you may contact any of the signatories below.

Sincerely,

Alexandra Gorman
Director of Science and Research
Women's Voices for the Earth

James Miller
President, Friends of the Bitterroot

Mary Wulff
Coalition for a Safe Lab

Cc: Dr. Fauci Director NIAID, Stephen A. Ficca, Governor Judy Martz, Senator Conrad Burns, Senator Max Baucus, Representative Dennis Rehberg, Mayor Joe Petrusaitis

Comment	Response
62-2	Please see response to comments 47-3 and 58-1.

Comments on the Supplemental Draft Environmental Impact Statement, Integrated Research Facility,RML, February 2004 Friends of the Bitterroot – Women's Voices for the Earth – Coalition for a Safe Lab

Comments:

62-3 1. The majority of the comments we submitted on the DEIS in July, were not addressed in the SDEIS.

In the document we submitted last July, we included at least 109 distinct substantive comments on the DEIS. Each comment was specifically numbered in the "Detailed Table of Contents" at the beginning of the document. Additional substantive comments were also included in the appendix to our document entitled "RML Draft EIS, Presented to the Town meeting June 25, 2003." We are resubmitting our original comments as we continue to believe that they are relevant to the proposed project and ask that they be addressed in the next draft of the EIS. (Our original comments have been appended to the end of this document.)

The NIH must follow the NEPA guidelines found in 40 CFR 1503.4 with respect to responding to public comments. 40 CFR 1503 states:

"*Sec. 1503.4 Response to comments.*

(a) An agency preparing a final environmental impact statement shall assess and consider comments both individually and collectively, and shall respond by one or more of the means listed below, stating its response in the final statement. Possible responses are to:
(1) Modify alternatives including the proposed action.
(2) Develop and evaluate alternatives not previously given serious consideration by the agency.
(3) Supplement, improve, or modify its analyses.
(4) Make factual corrections.
(5) Explain why the comments do not warrant further agency response, citing the sources, authorities, or reasons which support the agency's position and, if appropriate, indicate those circumstances which would trigger agency reappraisal or further response.
(b) All substantive comments received on the draft statement (or summaries thereof where the response has been exceptionally voluminous), should be attached to the final statement whether or not the comment is thought to merit individual discussion by the agency in the text of the statement."

None of the individual substantive comments constituted more than a page or two, and thus could not be considered "exceptionally voluminous". We fully expect, in accordance with 40 CFR 1503.4, that each one of our comments will be individually responded to in the final EIS.

It appears, however, (given the content of the current SDEIS), that NIH may have considered the many of our comments to "not warrant any further agency response". We look forward to seeing an official response to these comments which includes an explanation why each comment did not warrant further response "citing the sources,

Comment	Response
62-3	Please see the responses for comment 62-4 through 62-14.

authorities, or reasons which support the agency's position and, if appropriate, indicate those circumstances which would trigger agency reappraisal or further response."

2.) Comments that must be addressed through 40 CFR 1503.4 section (a) (2) "*Develop and evaluate alternatives not previously given serious consideration by the agency.*"

The NIH has received numerous requests from the public (throughout the EIS process) for a full analysis of alternative locations for the proposed IRF. According to the SDEIS, a full ten percent of comments received focused on a need for additional alternatives (SDEIS, p 1-9). We noticed that while some additional wording was added to the "rationale for dismissing" the proposed alternatives in the SDEIS, we were disappointed to see that there were still no alternatives in the document other than the proposed alternative and the no action alternative. While Congress allocated $66.5 million to NIAID in Public Law 107-117, Congress did not specify the location of the expansion in the law. We continue to believe this lack of analysis of alternative locations to be inadequate, especially for a project of this size and scope, and given the extensive public interest in alternative locations. According to 40 CFR 1502.14 the Alternatives section is "the heart of the environmental impact statement". We believe it deserves much greater attention.

Specifically, we would like to comment on the "rationales for dismissing" two of the proposed alternatives.

Section 2.2.2.1 of the SDEIS (pp. 2-17 and 2-18) proposes a rationale for dismissing the alternative to build the IRF in Bethesda, MD. It states, "*Based on the NIH Bethesda Master Plan, there are currently no available spaces on either campus capable of accommodating the Proposed Action. All unoccupied sites have been developed or are otherwise allocated.*" This appears to be saying that the Master Plan blocks the NIH from developing any new projects not already included in the Master Plan. However, a brief review of the EIS for the NIH Bethesda Master Plan reveals a very different opinion. That EIS clearly states:

62-4

" *The proposed action is a Master Plan that would guide and coordinate physical development of the NIH Bethesda campus in terms of buildings, utilities, roads and streetscape, landscapes, and amenities over the next 20 years in response to projected NIH administrative, research and infrastructure support needs (Draft NIH Master Plan, Main Campus, NIH, 1995). The Master Plan does not commit NIH to any of the projects proposed. Implementation of any project in the Master Plan is dependent on congressional funding... While the Master Plan makes relatively specific estimates for growth in campus population and facilities over the next 20 years, actual growth on campus will depend on future congressional and presidential policy decisions, as well as Federal budgetary constraints. Changes in national health policy could occur over the next decade, and NIH's mission could be significantly affected as a result. The Master Plan is a guiding map on how growth would take place on the Bethesda campus, were it to occur. The growth anticipated in the Master Plan may not occur to the extent indicated." (From 1.5 SUMMARY OF PROPOSED ACTION) (Emphasis added)*

"The Master Plan is a general planning document to guide physical development at NIH Bethesda. It is intended that it be flexible to meet changing NIH needs. NIH may deviate from the plan in siting some specific buildings or facilities. The Master Plan does not commit NIH to implementing specific projects

Comment	Response
62-4	The master plan does not block NIH from developing new projects in Bethesda. While development is flexible within designated land use areas, the land has to be vacant and available for construction. The SDEIS notes that there is no readily available land on the Bethesda campus. Relocating existing facilities, revising the master plan, demolition, etc., would require hundreds of millions of dollars and take up to 10 years, making this alternative unrealistic.

indicated or illustrated in the plan." (From Section 1.8 APPROVALS/ACTIONS REQUIRED BY OTHER GOVERNMENT AGENCIES) (Emphasis added)

(Source: Final Environmental Impact Statement, Vol. 1 of 2 for The 1995 Master Plan Available at: http://ocl.od.nih.gov/95EIS03.htm)

It is quite clear, that in the last two years that changes both in "national health policy" and the "NIH mission" have occurred with respect to its new charge to fight bioterrorism. In addition, congressional funding has already been allocated to the proposed IRF, whereas, it has not yet been allocated to several of the proposed projects in the Master Plan. Stating that "all unoccupied sites have been developed or are otherwise allocated" is simply inaccurate, given that the Master Plan is designed to be flexible, and not all parts of the plan have been funded. It is illogical that NIH would refuse to even consider prioritizing the placement of a congressionally funded building that directly meets the needs of a new Presidential directive on its Bethesda campus over an unfunded building that does not meet those needs. Therefore, we conclude that this SDEIS does not, in fact, present a rationale for dismissing this alternative. A fully developed alternative to build the IRF in Bethesda must be included in the next draft of the EIS.

62-5

Section 2.2.2.3 of the SDEIS proposes the rationale for dismissing the alternative of constructing the IRF at an alternate location (p.2-19). It states, "*Locating the BSL-4 laboratory at a separate location from the existing RML campus would eliminate the connected research on projects that use BSL-2 and BSL-3 facilities, making research inefficient and impractical.*" The proposed IRF includes new BSL-2 and BSL-3 laboratory space, meaning that connected research at different biosafety levels could still occur in the IRF even if it was at a separate location. In addition, it is very clear that NIH researchers are extremely efficient and adept at working with one another even when they are not located in the same building. The NIH-Bethesda campus houses thousands of scientists who work closely and regularly with their colleagues who are located in off-campus buildings in Rockville, MD several miles away. Regular shuttle bus services between the campuses as well as use of technology such as email, telephone and even videoconferencing make this arrangement perfectly workable and not at all to the detriment of the science performed by NIH. It is doubtful that the researchers at RML would be any less able to establish a good working relationship with researchers at a satellite facility located outside of the Hamilton town center, but within a few minutes drive. There is no reason why an off-campus building of Rocky Mountain Laboratories could not be constructed to house the IRF facility without "making research inefficient and impractical". The only other rationale proposed for dismissing this alternative was a conflict with "federal funding parameters". It is unclear how that conclusion can be drawn without either detailing what the cost of a satellite facility would be or what the federal funding parameters in fact are. According to 40 CFR 1502.23:

62-6

"Sec. 1502.23 Cost-benefit analysis.
If a cost-benefit analysis relevant to the choice among environmentally different alternatives is being considered for the proposed action, it shall be incorporated by reference or appended to the statement as an aid in evaluating the environmental consequences."

Comment	Response
62-5	This alternative still does not meet the purpose and need, as stated in the DEIS and SDEIS. Additionally, there is no environmental advantage over the alternatives that were considered in detail. Please see page 2-17 of the SDIES.
62-6	Please see response to comment 10-1.

62-7 Simply stating that the alternative fails to meet federal funding parameters is not a cost-benefit analysis. If the alternative is being dismissed as too expensive, a cost-benefit analysis must be done and included in the next draft EIS to verify this statement. Again, we conclude that no rationale for dismissing this alternative has been presented in this SDEIS. A fully developed alternative for building the IRF at an alternate location must be included in the next draft of the EIS.

3) Clarification needed on the study of biological weapons

62-8 According to the SDEIS, "*RML does not work on and will not work on or develop biological weapons as this is forbidden by a national security directive and international law. President Nixon, in 1969, agreed to a National Security Decision Memorandum (35), which renounced the use of lethal methods of bacteriological/biological agents. The U.S. signed...*" [SDEIS 1-1). Neither the National Security Decision Memorandum (35) nor the Convention cited prohibit the study of biological weapons for peaceful purposes - and in fact explicitly state study of biological weapons for peaceful purposes is allowed. We can only conclude that NIH continues to refuse to respond to continued questions as to whether or not any biological weapons will be present at RML. 40 CFR 1506.6 (f) states:

"*Make environmental impact statements, the comments received, and any underlying documents available to the public pursuant to the provisions of the Freedom of Information Act (5 U.S.C. 552), without regard to the exclusion for interagency memoranda where such memoranda transmit comments of Federal agencies on the environmental impact of the proposed action. Materials to be made available to the public shall be provided to the public without charge to the extent practicable, or at a fee which is not more than the actual costs of reproducing copies required to be sent to other Federal agencies, including the Council.*"

In order to comply with the CEQ, NIH must answer the following questions as a minimum:

62-9 1. Is there any law or regulation that prohibits the presence of an agent that was designed as a biological weapon to be present at RML? YES___ NO___.

62-10 2. Is there any law or regulation that prohibits the creation of an agent that is designed as a biological weapon to be present at RML for study for peaceful purposes? YES___ NO___.

62-11 3. Will agents be present that NIH will consider as classified information that they will refuse to disclose for any reason, including national security reasons? YES___ NO___.

62-12 4. Have there been agents present whose presence NIH has or would now consider as classified information or have or would refuse to disclose for any reason, including national security reasons? YES___ NO___.

Comment	Response
62-7	Additional information on the estimated cost of constructing an Integrated Research Facility at some new intramural location has been included in Chapter 2.
62-8	Page 4-5 states "NIH and its associated laboratories including RML, do not, and would not, work with weapons-grade material." This statement is also included in the DEIS on page 4-2.
62-9	No. Please see page 1-1 of the FEIS were this has been addressed.
62-10	No. Please see response to comment 62-9.

Remainder of responses on following page.

62-11 The general policy of the government is not to restrict information about fundamental research. (See National Security Decision Directive 189, September 21, 1985). However, it is possible that some information about research conducted at the RML could be classified. Information can be classified only under Executive Order 13292 (March 28, 2003), which sets very specific requirements for classification. To be designated as "classified," information that is owned, produced by or for, or controlled by the Government must fall into one of eight categories defined in the Executive Order, and disclosure of the information would have to be reasonably expected to result in identifiable or describable damage to the national security (i.e., national defense or foreign relations of the U.S.), including defense against transnational terrorism. Of note, scientific information falls in a classification category only when it is related to national security.

62-12 Yes. Agents that are on the NIH inventory that are currently classified have been present at RML in the past.

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62-13 5. Explain why the "worst case" scenario model for a release from RML was declared classified because, according to the author (verbal communication), they did not want to educate terrorists while at the same time NIH claims that biological weapons will not be "worked on" by RML.

62-14 4) Numerous citations from Chapters 3 and 4 were not included in the "Literature Cited" section on pages L-1-5.

Citations to credible documents are crucial to providing accurate information in a Draft EIS. Without a complete bibliography, it is impossible for the public to verify the accuracy of the claims made in the document. Where possible, for citations that are listed as "Name, year. Personal communication" which refer to letters, emails or other written correspondence, copies of the those documents must be included in the appendix for public review. The missing citations include:

P. 3-4
Bartos, 2003
Wilson, 2003 (This citation appears to be incorrect, the text has nothing to do with the safety of BL-4 agents.)

P.4-2:
Rollins, 2003
Bowers, 2003
Halladay, 2003
Dowling, 2003
Polumsky, 2003
Rose, 2003

P. 4-7:
Risi, 2003
Wilson, 2003a
Auch, 2003
Hoffman, 2003
Neff, 2003
Bartos, 2003 (Presumably, this should have been cited.)

P.4-8:
Harding & Byers, 1999
Johnson, 2003

P.4-10:
NSF (National Sanitation Foundation) 2002
First, 1996

Comment	Response
62-13	Please see response to comment 39-21.
62-14	These references have been included or corrected. We apologize for the oversight.

WHO, 2002
U.S. DOT, 2001
Rotz, 2002
Brachman, 1966
Risk Assessment Scenarios - No author or citation were provided for this risk assessment.

P. 4-26:
USGS, 2000
HDR, 2003

There may be others which we missed. The entire document should be carefully reviewed to ensure the bibliography in the Literature Cited section is complete and accurate.

62-15

5) Comments that must be addressed through 40 CFR 1502.14 (f) "Include appropriate mitigation measures not already included in the proposed action or alternatives."

In section 6.2.3 of our comments on the DEIS we listed a series of reasonably foreseeable scenarios. They included:

6.2.3a Staff infections that are isolated to lab environment.
6.2.3b Staff infections that result in a community wide epidemic.
6.2.3c Release of infections through escaped animals.
6.2.3d Release of infectious prions through the incinerator including an assessment of recombination after cooling in the smokestack.
6.2.3e Release of infectious agents through water via sewage, wetlands, or surface water.
6.2.3f Release of infectious agents through ground due to spills or purposeful dumping.
6.2.3g Release of infectious agents when being transported.
6.2.3h Release of infectious agents through water via sewage, wetlands, or surface water.
6.2.3i Release of infectious agents because of an out of control fire.
6.2.3j Release of infectious agents through intentional acts by a staff member.
6.2.3k Release of infectious agents due to a terrorist attack with a bomb or aircraft.
6.2.3l Release of infectious agents due to the safety committee and staff failing to understand the behavior and danger of a new pathogen under study.
6.2.3n Release of infectious agents due to a failure of the safety systems.
6.2.3o The causal release environment: accidental spill, fire, terrorist explosion.
6.2.3p Release through steam exhaust.

We asked NIH to disclose the risks of these scenarios. These risks were not adequately assessed. And some of the above scenarios were never considered, addressed or even mentioned in the SDEIS. We again ask that the risks from these scenarios be analyzed in the next DEIS. In addition, we ask that mitigation measures be included in the next DEIS for those risks which cannot be eliminated.

Comment **Response**

62-15 Measures are to be included "to mitigate adverse environmental impacts" (CEQ 1502.16(h)). Since there were no adverse impacts identified from the items listed, no mitigation is necessary. Please see Section 1.7.3 where comments on the potential increased threat of outbreak are addressed.

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62-16 6) Detailed risk analysis and mitigation measures (such as the emergency plan) must be included in the next DEIS for the risks of laboratory-acquired infections.

Appendix D of the SDEIS "Review of the Biocontainment Laboratory Safety Record" provides clear evidence that accidents do occur in BSL-4 labs that can lead to laboratory-acquired infections, and that laboratory-acquired infections have occurred at Rocky Mountain labs BL-2 facilities. The conclusion of this report, however, states "*The zero numerator of infections in these three laboratories and the huge denominator of exposure hours make it impossible to provide a number for "risk of infection" to either laboratory workers or outside communities.*" It appears to be saying that because an laboratory-acquired infection has never occurred at nay of the three BL-4 labs investigated, the risk of such an infection cannot be quantified. Interestingly enough, in Chapter 4, a quantitative risk assessment of accidental release of anthrax (a scenario which has presumably never happened at a BL-4 lab either) was able to calculate a risk as precise as ".000011 spores released to the environment." Seeing as the original DEIS claimed the risk of release to the community "cannot be quantified", and the SDEIS followed up by actually quantifying it, it seems likely that the risk of a laboratory-acquired infection can in fact (and should) be quantified in the next DEIS.

In addition, extremely pertinent information on laboratory-acquired infections is missing from Appendix D. This report shows that multiple accidents including needle sticks, animal bites, tears in gloves and suits and containment failures occurred in the three BL-4 labs researched. While it is fortunate that none of those accidents led to clinical infections, it is clear that any of those accidents could have led to an clinical infection. It is well-documented that needle-stick accidents (for example) are a pathway for transmitting disease. Clearly, the fact that no clinical infections occurred in the three labs had nothing to do with safety aspects of a BL-4, or characteristics of BL-4 diseases, but rather is directly related to the quality and timing of the care the exposed worker received. As soon as such a significant laboratory accident happens, the risk of a clinical infection can only be lessened by the quality and timing of medical treatment of the exposed worker. How, where, how soon were the exposed workers at the three labs given treatment for their exposure? What experience, knowledge, equipment was available to the healthcare providers who treated the exposed workers? This pertinent information was not included in the report, but should have been.

The very best (and likely, only) mitigation measure for the risk of laboratory-acquired infections is a well structured, well funded emergency plan. The current lack of an emergency plan is a serious omission. It is the document that provides the details of how exactly the risk of an laboratory-acquired infection would be handled. It is the only document that allows the public to know that our current medical and emergency resources are adequate to mitigate this risk. Clearly we cannot accurately assess the risk, which is dependent on the adequacy of our community's ability to respond, until we know how well we will be able to mitigate it. The NIH cannot legally wait until after the NEPA process is finished to ascertain the magnitude of the risk of an incurable, fatal infection in an RML employee. The emergency plan must be included in the next DEIS.

Comment	Response
62-16	Please see response to comment 62-15.

62-17 7) Mitigation measures involving Marcus Daly Hospital and St. Patrick Hospital must be included.

Section 4.2.1.1 of the SDEIS briefly discusses "emergency response". It states, "Mr John Bartos of Marcus Daly Hospital…did question whether capital improvements would be needed should a life-threatening injury be transported to Marcus Daly Hospital for stabilization…"(P. 4-7). On Page 3-4, it states that Marcus Daly Hospital could not handle more than 10 emergency patients. Thes two statements create significant public concern about the adequacy of Marcus Daly Hospital to handle a life-threatening emergency at the lab. No other BL-4 lab in the country is in a location that faces this problem. All BL-4 labs are within very close proximity to large medical facilities capable of handling significant numbers of highly infectious emergency patients. The problem in Hamilton is not unsolvable. Mitigation alternatives which provide additional resources for Marcus Daly Hospital to be better prepared to handle an emergency at the lab must be included in the next DEIS.

Similarly, little detail is provided on the abilities of St. Patrick Hospital to respond to an emergency. Page 4-7 states "*St. Patrick Hospital meets all required standards for handling infectious disease cases.*" This statement neglects to mention how many highly infectious emergency patients St. Patrick Hospital would be able to handle. This is pertinent information in determining the hospital's ability to handle a major accident at the lab. Mitigation alternatives which provide additional resources for St. Patrick Hospital to be better prepared to handle an emergency at the lab must be included in the next DEIS.

62-18 8) Inaccuracy regarding claim that it takes 48 hours for an exposed person to become contagious.

Section 4.2.1.1. includes a section on "Agent Communicability and Treatment" which states: "*Infectious disease specialists now know that it takes at least 48 hours for an exposed person to become contagious, regardless of microbe type.*"(P. 4-7) Firstly, there is no citation included to back up this incredible claim. Secondly, the claim directly contradicts information provided by NIH in Appendix B of the SDEIS "Characteristics of Diseases Studied at RML". In Table B-2 in this appendix, it clearly shows that both plague and Congo-Crimean hemorraghic fever can have incubation periods of just one day before the first signs of disease appear. This means that these particular diseases have been known to be infectious in as short a time period as 24 hours. In addition, diseases such as Nipah virus encephalitis and the South American arenaviral hemorrhagic fevers have "unknown" incubation periods. No certainty can be expressed in terms of how long it takes an exposed person to become infectious for these BL-4 diseases.

The second claim that is made in this section is "*This [the 48 hours] provides adequate time to transport and initiate treatment to benefit the individual and isolate a potentially exposed person from the greater population.*" This claim assumes that the exposure is identified immediately by the exposed worker. In the case of a ripped or torn suit, the exposure may not be identified until the next day when the suit is worn again. Clearly

Comment	Response
62-17	Please see response to comment 62-15.
62-18	This statement should have been attributed to Dr. George Risi, which has been included in the FEIS. Communicability and "first signs of disease" are not the same thing, and it does not mean that infection can be passed within 24 hours.

these two claims are incorrect and misleading and should be changed or removed in the next DEIS.

9) Inaccuracy regarding claim about temperature required for certification of RML's incinerators.

Section 4.2.1.1 of the SDEIS includes a section on "Inactivation of materials infected with agents of transmissible spongiform encephalopathies (prion diseases) which states: "*The incinerator at RML is a Consumat 325 Incinerator. Both state and federal authorities license it as a hospital medical infectious waste incinerator. To be certified as such, the two-stage incineration process must allow for a minimum of 4 hours of burn time at approximately 1800°F (983°C)*" (p4-9). Once again, there is no citation given for this claim. Close inspection of RML's Air Quality Permit 2991-04 reveals that there is no temperature requirement for the incinerator. Federal regulations on medical waste incinerators, found in 40 CFR 60 Subpart Ce, also omit any requirements for minimum burn time or temperature. Montana's state regulations for medical waste incinerators are identical to the federal regulations. In addition, a presentation by Dr. Caughey made at a December 2002 RML CLG meeting indicated that the RML incinerator is fired for a minimum of four hours at 1400°F (760°C) and then at 1800°F for just a few seconds. There is no indication from MT DEQ that RML has asked to change their incinerator firing temperature or include a minimum temperature requirement in their permit (Source: Eric Merchant, MT DEQ, personal communication). The SDEIS should have been more carefully factchecked before being released to the public. This misleading inaccuracy must be fixed in the next DEIS.

62-19

10) Inaccuracy regarding claim about incineration as "method of choice" for inactivating pathogens.

62-20

Section 4.2.1.1 of the SDEIS also states: "*High temperature incineration continues to be the method of choice for medical and veterinary wastes as it has been demonstrated to be effective at inactivating all types of pathogens*" (P. 4-9). Again, there is no citation given for this inaccurate claim. In reality, incineration is no longer considered the method of choice for medical and veterinary wastes in the U.S. due to the recently promulgated strict federal regulations which were put in place to help reduce the excessive air pollution problems caused by incinerators. Since these regulations were promulgated a few years ago, hundreds of medical facilities around the country have chosen to shut down their waste incinerators and have substituted safer, cleaner, equally effective non-incineration technologies such as autoclaves. Even the NIH in Bethesda does not consider high temperature incineration the "method of choice" as their incinerator was shut down several years ago. In Montana, the also trend has been quite clear. In the last few years the medical waste incinerators at Fort Harrison V.A.M.C. in Helena, St. Joseph's Hospital in Polson, Mahlstrom Air Force Base in Great Falls, and Corixa Corp in Corvallis have all been replaced with non-incineration alternatives. RML operates the only remaining

Comment	Response
62-19	The RML Incinerator is subject to compliance with 40 CFR 60, Subparts Ce and Ec. Monitoring requirements for a Medium Intermittent Hospital Medical Waste Incinerator include that facilities establish the appropriate maximum and/or minimum operating parameters for each control system per 40 CFR 60, Subpart Ec, 60.56c and 60.57c. The current operational requirement for secondary chamber temperature is in excess of 1800°F and load input is mechanically locked out until the upper chamber reaches that temperature. Minimum or maximum incinerator operating parameters are established from air emission operational testing data. These parameters are submitted to the State for review and approval. 40 CFR 60, Subpart Ec, 60.51c relating to definitions states under *shutdown* that for intermittent HMIWI, shutdown shall commence no less than 4 hours after the last charge to the incinerator. One minute monitoring of all operating parameters is required by both State and Federal regulations and documentation verifies that the load input does not occur until the temperature of the secondary chamber reaches 1800°F and that that temperature is maintained until 4 hours after the last load input.
62-20	The DEIS, SDEIS, and FEIS contain a citation to support this statement. Additional information and a reference have been added to the FEIS (see pages 4-9 and 4-23).

medical waste incinerator in the state. This misleading and incorrect claim must be removed in the next DEIS.

11) Confusing language in describing risk.
PAGE S-4 of the SDEIS states "*Theoretically, human error or multiple, simultaneous mechanical failures could lead to accidental release of biological materials from a biosafety laboratory. The overall safety record of biomedical and microbiological laboratories also indicates that there is not a risk of accidental release.*" Then later on this page it states that "*The overall safety record of biomedical and microbiological laboratories indicates that there is not a significant risk of accidental release*".
These statements are confusing and potentially seem to contradict one another. The first claims that an accidental release could happen yet there is no risk of it happening. The second merely claims that there is no significant risk of an accidental release happening. This section should be reworded for clarity in the next DEIS.

12) Additional questions not answered and analyses not included in the SDEIS.

62-21 PAGE 1-13 of the SDEIS states that "No construction on the IRF has occurred." However, the contractor hired by NIH has purchased several lots of land adjacent to the lab. Why isn't this addressed anywhere else in the SDEIS?

62-22 PAGE 2-6. SDEIS states that the alkaline hydrolysis process tissue digester would inactivate prions. Is this digester in the budget for the proposed IRF? Or is the digester also planned for RML in the case of the no action alternative. It is not included in the list of upgrades in Section 2.1 on Page 2-1, even though it would clearly act as equipment useful to existing labs working on prion diseases on the RML campus. Please clarify.

62-23 PAGE 2-7 states "HEPA filters would be changed every five years". Is this adequate? How often would they be inspected/checked to assure they are functioning correctly?

62-24 PAGE 2-12 states "*Generation of low-level radioactive waste is anticipated to increase about 30 percent with construction of the Integrated Research Facility... Use of sulfur 35 is likely to increase*," Sulfur 35 emits a weak beta particle and its half-life is 87.4 days. Analysis of the health risks (for Hamilton citizens and those that consume water and live in or near Hamilton area) of low-level radiation into the Hamilton City Sewer system should be included. Health effects of low-level radiation on fish and wildlife should be included.

62-25 PAGE 2-16. Please include an analysis of safety for transport and disposal of all long half-life radioactive waste, in and out of Hamilton, along the route transported, as well as at the disposal site.

62-26 PAGE 3-19. "*Sludge is then composted during warm-weather months. The compost is made available for land application but is not allowed for use on vegetable gardens*". Include an analysis of health risks to animals that may graze on the land where sewage sludge is applied. Health problems in animals that graze on the land could devastate the

Cont on next page

Comment	Response
62-21	Purchase of land by a contractor is not construction.
62-22	Please see Section 2.1.3 for a description of the proposed action.
62-23	Please see Section 2.1.3 of the SDEIS. As stated, the filters would be certified once a year, which includes testing.
62-24	RML has a very effective decay-in-storage program for sulfur-35. The sulfur-35 containing liquids are stored for decay in a locked double containment storage area.
62-25	RML has shipped only naturally occurring radioactive materials on one occasion. The designated destination for any radioactive waste shipped from Montana is the U.S. Ecology Facility in Richland, WA. Brokers and transporters must meet all requirements of DOT and NRC.

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62-26 cattle, farm, and ranching industry in Montana and thus have an adverse effect on the economy. Include a study or analysis of the possibility of transmissible spongiform encephalopathies being transmitted to grazing animals in this manner.

62-27 PAGE 4-1. With regard to animal deliveries. How are the animals caged, transported and then handled before and after arrival for delivery at Rocky Mountain Labs? Who accepts delivery of such animals? How are the animals handled and transported to holding facilities after arriving at RML? Who is responsible for handling animals delivered to RML?

62-28 PAGE 4-6. Manipulation by man can make diseases more virulent. Will RML be "manipulating" diseases to make the more virulent? please include details explaining this process and under what circumstances it may occur at RML.

62-29 PAGE 4-11 through 4-14.
Risk to the community must be seriously considered and mitigation alternatives must be analyzed. The SDEIS claims that the potential risk of a release of infectious agents from the proposed lab is "negligible". Any risk, no matter how small, of an epidemic of an incurable fatal disease in our community should not be dismissed as "negligible". The potential consequences are much too great to be considered "negligible". Even if the risk is very small - if it cannot be eliminated the NIH must show how it will be mitigated. This means the EIS must clearly illustrate the plan for how a "worst case scenario" will be handled.

62-30 PAGE 4-11 through 4-14. Scenarios should be included where a pathogen DOES get out of the lab, for any reason, whether by accident or covert design, and then show how the situation would be mitigated.

62-31 PAGE D-2. The review of work done included only intramural laboratories. The review of accidents, exposures and deaths should include all laboratories in the United States.

62-32 PAGE D-4 and D-11. The last sentence of this report says "This report is included in the Final Environmental Impact Statement of the Integrated Research Facility." This must be inaccurate as (hopefully) the Final EIS has not yet been written. It appears that this report was written and released prior to the release of the Supplemental Draft Environmental Impact Statement and may show predetermination of the proposed project at RML.

13) Comment on the List of Preparers.
The SDEIS makes a point of including RML personnel in order to attempt to convince the public that the preparers of the SDEIS are qualified. However, of those names added, only the authors of the "worst case study" and Appendix D appear to have been "primarily responsible for preparing". The other additions are reviewers and do NOT appear to be the original authors of any portion of the document.

62-33 14) The Worst Case Scenario (P. 4-11) is inadequate for assessing risk.

Comment	Response
62-26	Additional information on disposal of prion contaminated material has been included in section 2.2.1.1 of the FEIS. These disposal methods preclude any risk of contamination of sewage sludge from RML prion research. All other liquid waste is fully decontaminated prior to release into the wastewater stream.
62-27	Animals are purchased from USDA inspected and certified vendors. Transport cages meet USDA specifications. Once delivered to the climate controlled receiving area, Veterinary Branch Technicians transport the cages/animals to the animal facilities. Health checks are performed and animals are transferred to clean cages. The Chief of the Rocky Mountain Veterinary Branch is responsible for the handling procedures of animals delivered to RML.
62-28	No experiments designed to enhance the virulence of any biologic agent are envisioned. Frequently natural disease agents are made less virulent by handling in tissue culture.
62-29	There is no indication or history to indicate that the Integrated Research Facility has the potential to cause an epidemic of any size. It is, therefore, a negligible risk, effectively no risk, that does not need to be mitigated and is appropriately analyzed and disclosed in the SDEIS.

Remainder of responses on following page.

62-30 The Integrated Research Facility would be designed to never allow a pathogen to escape the laboratory, and history proves the design to be effective in achieving this goal. Please also see response to comment 62-98 where HEPA filters are discussed.

62-31 Since the Proposed Action is an intramural facility, it is appropriate to review the operation of intramural facilities for a history of their safety. Please also see response to comment 63-22. Incidents in other US and international labs do not bear on the results of NIH laboratories as NIH has no control over operating procedures of other laboratories. The NIH would be responsible for the safety in the Integrated Research Facility and maintain its high standards. These standards have resulted in the outstanding safety record cited in Appendix E.

62-32 The report was placed in the document before the decision was made to issue a supplemental draft. The wording should have been changed to say as much. It is also included in the FEIS.

The report was prepared as an important part of the NIH's full analysis of the environmental impacts of the proposed action. Without the report, the NIH would not be able to make an informed decision on the action. The NIH will not decide which action to take until after the Final EIS is published and the NIH issues its Record of Decision.

62-33 Please see response to comment 39-21.

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The Worst Case Scenario (P. 4-11) is inadequate for assessing risk because:
1) The model and its assumptions are classified - giving the public no way to review or challenge assumptions made. Other, unclassified approaches would be equally or more valid.

2) The scenario does not deal with the issue that has been repeatedly raised in public comments: An infected staff member spreading an infection the community.

62-34

15) Most of our comments regarding risk were ignored in the SDEIS.

These include questions about the effectiveness of HEPA filters; assessing risk based on the probable increase of experiments by a factor of ten (The Appendix D analysis includes the assumption that the probability of a release is a statistically independent function of the number of experiments performed).

16) Lack of discussion of how safety rules will be enforced.

The SDEIS ignores the issue raised by NIH's own disclosure of repeated unsafe practices and staff ignoring safety rules. While the SDEIS discusses the safety rules, it contains no statement regarding how those rules would be enforced. Given RML's record, the risk analysis must assume that safety and fire safety rules continue to be violated at current rates.

17) Documentation to back up claims should be included in appendices of the SDEIS.

It is standard practice in an EIS to include full copies of reports, analyses and other communications which were produced in order to provide information for the EIS. This is true especially when the information is not otherwise publicly available. The following documents must be included as appendices in the next draft of the DEIS.

- Air Dispersion Modeling for the RML incinerator (Doucet and Mainka, 1999)
- BSL-4 Facility Noise Analysis Report (Big Sky Acoustics 2002)
- Geotechnical investigation for proposed IRF (GMT Consultants, 2002)
- Full report of Quantitative Risk Assessment Scenarios addressed in Chapter 4
- Complete data from Dr. Johnson's report in Appendix D. (It is unclear why a table of the Safety Record for RML is included but not a similar table for the three BL-4 labs researched. The summary of safety record information from these facilities is not sufficient.)
- Hemisphere's report on current water usage at RML

18) Typo on Page 4-11
On page 4-11, it should read "The Public Health Preparedness and Bioterrorism Response Act of 2002" not 2001. (It was signed by President Bush June 12, 2002.)

19) Analysis of estimated water usage on p. 4-25 must be corrected and clarified.

Comment	Response
62-34	Please see Section 1.7.1 where comments on additional information were addressed. Also see Section 1.7.3 where comments on risk were addressed.

The analysis of water usage on p 4-25 is highly confusing and seemingly inaccurate. It should be made clear if this analysis was prepared by a water consultant - or by Maxim Technologies. If the analysis was prepared by Maxim, citations should be included for the varied assumptions made in the analysis. Specifically, it states:

"*Assuming that thirty percent of the new employees live in Hamilton…*" What is the basis for this assumption? Is that the known ratio of current RML employees? If so, this information should have a citation to back it up. Otherwise, to be conservative, the assumption should be that all 100 new employees live in Hamilton.

"*If each person uses an average of 150 gallons per day, there would be an average increased daily usage of 11,250 gallons per day per household.*" Actually, with 2.45 person per household, the increased daily use should be 367.5 gallons per day per household (150 x 2.45). For all 30 houses combined, the average daily use would be 11,025 gallons per day. Also, a citation should be provided for the estimate of 150 gallons per day per person.

"*Assuming that all thirty new households are single family dwellings on half acre lots and use 1,305 gallons per day to irrigate lawns for 120 days per year, the average amount of water used per household for irrigation would be 12,871 gallons per day.*" The first part of this sentence seems to be be saying that each household uses 1,305 gallons per day to irrigate, which contradicts with the conclusion of the sentence which says that each household uses 12,871 gallons per day for irrigation. If the 1,305 gallons per day per household number is correct, a citation should be provided for this estimate. It should be made clear that during the 120 irrigation days the water usage would be 39,150 gallons per day for all 30 households (1,305 x 30).

"*If the estimated increase usage from RML is added to the new resident usage and irrigation, the total increase would be 41,121 gallons per day or 28.5 gpm.*" It appears that this would not be true during the 120 irrigation days. Estimated new usage at RML (17,000 gallons per day) plus estimated daily household use for 30 houses (11,025 gallons per day) plus estimated daily irrigation use for 30 houses (39,150 gallons per day) equals and increase of 67, 175 gallons per day. This should be clarified.

"*… the available capacity of 226 gpm.*" A citation for this statistic should be provided. Presumably, given the enormous amount of water used for irrigation during the summer months, the "available capacity" of water in Hamilton is greater during the winter than during the summer. Does the 226 gpm figure refer to summer capacity or winter capacity? If it is an average of the whole year, the available capacity for summer should be calculated. And the estimated increase in use during the summer should be compared to this summer capacity number to ensure adequate supply during the time of greatest demand.

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Appendix A: Unified Comments submitted on the DEIS, July 2003

Executive Summary

Unified public comments of Coalition for a Safe Lab, Friends of the Bitterroot and Women's Voices for the Earth on the National Institutes of Health proposed BSL-4 Integrated Research Facility in Hamilton, Montana

The members of Coalition for a Safe Lab, Friends of the Bitterroot and Women's Voices for the Earth have demonstrated considerable interest and concern about the proposed BSL-4 facility's impacts on our communities. Our interest is to ensure that the public process generates meaningful discussions, disclosures and analyses between National Institutes of Health, Rocky Mountain Laboratories and the public so informed decisions can be made.

Our groups wish to thank the community and members of the public who have given thoughtful time and consideration to the proposed BSL-4 expansion. A commensurate commitment by National Institutes of Health needs to be reflected in the discussion and through disclosure of critical information that the public has asked for to assess the risks and establish effective mitigation actions for a BSL-4 facility.

The Supplemental Draft Environmental Impact Statement submitted by National Institutes of Health is entirely inadequate in its' analysis of safety, health, social, economic and environmental issues and must be corrected with substantive information republished for public comment.

The impact statement exhibits substantial bias toward expansion of a BSL-4 facility in Hamilton, Montana. Furthermore, the public record shows a stance of predetermination and irrevocable commitment of resources for locating a BSL-4 facility at Rocky Mountain Laboratories prior to requesting input from the public on the decision.

The scope of the impact statement was arbitrarily limited to avoid consideration of valid and publicly supported alternatives. The location of alternative sites should not be dismissed based on a lack of budgetary, financial, or logistical analysis in the impact statement. An expanded BSL-4 capability is part of a federal effort to prepare contingencies for responding to the use of infectious diseases as agents of bioterrorism. By adopting a purpose that precludes reasonable consideration of alternatives, the impact statement exhibits an indefensible bias that cannot be rectified in this document.

National Institutes of Health has failed to propose adequate measures mitigating safety, health, social, economic and environmental impacts from the BSL-4. The lack of appropriate mitigation measures makes the proposed action unacceptable.

National Institutes of Health failed to take a hard look disclosing the risk of an infectious disease or biological agent escaping, or accidentally or intentionally being released into our environment. Such an analysis is a requisite requirement for the public to fairly judge the

cost, benefits and risks of locating a BSL-4 facility in Hamilton, Montana.

The impact statement fails to disclose and mitigate fire protection, emergency planning, preparedness, response and communication measures to protect lab workers and the community in the event of a release of an infectious disease, biological agent or hazardous materials. There is also a lack of discussion concerning coordination with Local and State Emergency Planning Agencies and Task Forces for responding to emergencies, and preparing contingencies for protecting the safety and health of affected communities.

The impact statement fails to effectively incorporate pollution prevention strategies to mitigate noise, lighting, air and water pollution, energy consumption, solid, hazardous and radioactive materials use and treatment, and generation and treatment of pathogenic wastes. The impact statement also fails to satisfy public concern over financial impacts to local government infrastructure, available medical services, the safety of employees and nearby communities and our environment.

The impact and risk of lab-acquired infectious diseases for workers at Rocky Mountain Laboratories is not discussed yet it is known that at least three such incidents have occurred at the facility in Hamilton, Montana as a result of poor adherence to standard biosafety practices and faulty safety equipment.

The impact statement fails to adequately disclose:

* Impacts on nearby neighborhoods including noise, transportation, traffic safety, and property values for households and businesses located within the vicinity of the Rocky Mountain Laboratories facility.

* Impacts on the environment including air, water, wetlands, endangered species, and the use, treatment and disposal of solid, hazardous, radioactive and pathogenic wastes.

* Real and potential conflicts between the proposed action and objectives of land use plans including Ravalli County's Growth Policy which protects identified community values.

In summary, a number of socio-economic, health, safety and environmental costs the public raised were not satisfied in the impact statement. The absence of meaningful measures to mitigate these impacts underscores the inadequacy of the purported benefits of locating a BSL-4 facility in rural Montana.

The members of Coalition for a Safe Lab, Friends of the Bitterroot, Women's Voices for the Earth have provided detailed comments requesting disclosure of critical information that the public needs to make an informed decision about locating a BSL-4 facility at Rocky Mountain Laboratories in Hamilton, Montana. The National Institutes of Health has an obligation to provide that information to the public.

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1. Our members will be affected by this project.

Our groups have over 1,000 members who live, work, recreate, run businesses, pay local taxes, and own property in the immediate area around the proposed project.

The proposed BSL-4 facility's:

- Potential economic benefits,
- Potential improvements in treatment from RML research,
- Potential economic reverses,
- Net impact on taxes,
- Potential environmental damage, and
- Risk of serious illness or death affects our members directly.

2. The document is not a valid Draft EIS and should be corrected and republished for Public Comment.

CEQ 1502.9 requires a Draft EIS to be redone and republished for comment if it fails to meet the requirements of NEPA:

> "The draft statement must fulfill and satisfy to the fullest extent possible the requirements established for final statements in section 102(2)(C) of the Act. If a draft statement is so inadequate as to preclude meaningful analysis, the agency shall prepare and circulate a revised draft of the appropriate portion. The agency shall make every effort to disclose and discuss at appropriate points in the draft statement all major points of view on the environmental impacts of the alternatives including the proposed action."

2.1 The DEIS exhibits substantial bias toward the Proposed Action.

The General Administration Manual, HHS Part 30, Environmental Protection includes detailed procedures for compliance with NEPA for agencies within the Department of Health and Human Services (HHS). These procedures clearly state the types of alternatives that must be considered, as well as rules regarding which alternatives cannot be automatically excluded. It also states that:

"*Draft environmental impact statements shall not exhibit biases in favor of the proposed action.*" (30-30-30 B.1.)

2.1.1 Bias is evidenced by establishing a purpose that by definition allows for no alternatives other than the No Action alternative.

2.1.2 Several of the analysis of impacts in the DEIS only disclose the positive aspects of the agencies preferred alternative and fails to disclose the negative impacts – a further evidence of bias.

For example, the discussion of the impact of the proposed action regarding income in paragraph 4.3.1.1 under the discussion of Economic Resources only list the wages and economic activity multipliers due to construction and additional employment in the laboratory. The negative economic impacts that would result from an event that infected people in the community are not mentioned in spite of the fact that there is a "Potential added risk to the community from the Proposed Action…" (DEIS 4-2).

62-35

In fact, the DEIS should analyze and disclose the impact on real estate values, rental income, and the local economy if an infection is released to a community from a biological laboratory anywhere in the country and internationally. Such an event is likely to be newsworthy and increase the perception that living near a BSL-4 laboratory is

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62-35

dangerous with the result of decreased property values and business activity around all such laboratories. As the probability of a single event rises with the increased number of laboratories and experiments within those laboratories, the possibility of accidents increases. A historical precedence for such a connection is the nuclear industry and the Three Mile Island release of nuclear material.

As the discussion continues in section 4.3.1.1 we see the discussion going from a discussion specific dollar amounts in the millions contributed to the economy to the net impact on public finance as a factor that "cannot be predicted". Clearly, the authors of the document have the tax structure for the United States, Montana, and Hamilton available. Clearly, they had estimates of the number of new households available (DEIS 4-2). When the dollars that will be paid in wages will favor the NIH's proposed alternative, we see specific numbers backed up by a complete study in the list of references. Yet, when the outcome is likely to be negative the NIH suddenly finds that is "cannot be predicted."

The discussion of Community Safety in 4.2.1.1 is highly biased claiming that the added risk "cannot be effectively quantified". NIH Uses this as an excuse to make unsubstantiated claims to dismiss, without analysis the community safety issues raised in scoping. The claim: "In more than 30 years of working with BSL-4 agents in the U.S., there has never been a confirmed release to a community from a laboratory (Wilson 2003)" (DEIS 4-2) is made to appear to be substantiated with a reference in the apparent hope the reader will not check the bibliography. When we look up the reference, we find this claim is a verbal communication from a staff member from the very agency attempting to promote the proposed alternative. In fact, the press reports that there is DNA analysis evidence that the anthrax powder that appeared in our nation's capital came from a BSL-4 U.S. government lab.

62-36

The section goes on to state that: "It is not specifically known what agents would be studied at the Integrated Research Facility." NIAID certainly knows the agents that would be candidates for study. Some of BSL-4 assigned agents are listed in Appendix B, but the risks and consequences to the community are not discussed in anywhere near the detail needed for the reader to assess any risk.

The attempt to dismiss scoping comments related to the use of "weapons-grade material" is unsubstantiated, with no reference to a regulation or agency commitment to preclude the study of weapons grade material – an apparent contradiction to the stated purpose of studying agents that might be used for bioterrorism.

> "As a result, President Bush tasked the National Institute of Allergy and Infectious Diseases (NIH) to increase its research into the development of safe and effective countermeasures to protect the public against the threat of biological agents that might be used for bioterrorism." (DEIS S-1).

At the same time this section dismisses any risks with unsubstantiated and misleading claims, it provides more specific details on safety measures that cast a positive light on the proposed alternative.

Comment	Response
62-35	Please see Section 1.7.3 where comments on the social and economic impacts were addressed, and Section 4.2.1.1, Community Safety and Risk, where Risk Assessments are addressed.
62-36	Please see section 1.7.3 where comments requesting a full description of agents were addressed.

2.1.3 The DEIS fails to study and disclose in detail the No Action alternative to provide the public with a baseline by which to compare, contrast and consider the merits of No Action and the Proposed Action.

For example, Environmental Consequences:

62-37

Emissions
"Emission would remain at current levels under the No Action alternative."(DEIS 4-14) Though current levels of pollutants may remain near current levels, there are environmental consequences under the No Action alternative.

62-38

Water Supply
"The No Action alternative would not have an impact on water supplies in Hamilton or the Bitterroot Valley. " (DEIS 4-15) Clearly, current water use by RML does have an impact on the environment.

62-39

Wastewater
"The No Action alternative would not have on impact on wastewater treatment in Hamilton. The No Action would not have an impact on the solids handling capacity of the plant." (DEIS 4-15) Clearly, wastewater discharge by RML does have an impact on the environment.

The DEIS fails to provide the minimum standard for analysis and disclosure of impacts for the proposed and no action alternatives and must do so.

2.2 The DEIS fails to meet the standard for depth and thoroughness of analysis of impacts.

The following areas are examples of areas in which the DEIS fails to provide meaningful analysis or disclosure:

62-40

Social Resources

Housing: No discussion of impact on open space, farmland, wildlife, noxious weeds. *The indirect and cumulative impacts of housing employees on these and other resources must be analyzed and disclosed.*

Community Safety: No analysis of risk or disclosure of consequences to the community.

Education: No analysis of the impact on education except for unsubstantiated claims that education capacity is adequate.

In the following comments, numerous other examples of failure to provide the analysis required by a DEIS are cited.

Comment	Response
62-37	Please see Section 1.7.3 where comments on air quality were addressed.
62-38	Please see Section 1.7.3 where comments on the impacts on the City of Hamilton water supply were addressed.
62-39	Please see section 1.7.3 where comments on the Proposed Action's effects on the City of Hamilton water and wastewater systems were addressed.
62-40	Effects on open space (including farmland) have been added to Chapter 4 of the FEIS. Please see Section 1.7.3 where comments on the effects on wildlife, noxious weeds and community safety were addressed. The school superintendent is the official considered as the credible source on the status and capacity of schools in the district.

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2.3 No one who prepared the DEIS appears to have the experience in safety or microbiology to assure the public that the DEIS has the scientific integrity required by NEPA.

62-41

The list below shows the entire list of qualifications for the preparers of the DEIS. We see no documented experience in microbiology, health, or safety. In fact, the preparer assigned to Human Health is educated in zoology and fish and wildlife management. The preparer assigned to community safety is educated in environmental studies and biology. (DEIS-List of Preparers)

- BA/Urban Affairs
- BS/Petroleum Engineering
- BS/Geography
- MS/Hydrogeology, BS/Biology
- MA/Interdisciplinary Studies (History/Anthropology), BA/Geology
- MS/Hydrogeology, BS/Geology
- MS/Environmental Studies, BS/Biology
- BS/Earth Sciences (Geology and Soil)
- MS/Geology (Hydrogeology), BS/Earth Science (Geology)
- BS/Forest Resource Management
- PhD/Environmental & Forest Biology, MS/Zoology, BS/Fish & Wildlife Mgmt.
- Graphic Artist

For these reasons the DEIS fails to meet both the National Environmental Policy Act and Health and Human Services requirements for a Draft Environmental Impact Statement. In order to comply, a compliant DEIS must be prepared and republished for public comment.

Comment	Response
62-41	Please see section 1.7.5 where comments on the preparers of the DEIS were addressed.

3. Project was predetermined and irrevocably committed resources.

3.1 The decision to build a BSL-4 laboratory at RML was made prior to requesting scoping comments from the public.

This is evidenced in articles written by the Director of NIH (FAUCI, 2002). On June 10, 2002, Dr. Fauci, the Director of NIH announced to Congress the decision to put a BSL-4 lab at Rocky Mountain Laboratory in Hamilton, Montana.

Excerpt from Homeland Security: The Federal and Regional Response Field Hearing before the Subcommittee on Environment, Technology, and Standards Committee on Science, House of Representatives, One Hundred Seventh Congress Second Session; June 10, 2002:

Mr. BARTLETT. "Thank you very much. I wonder if you could spend just a moment letting the audience know how unique a Level 4 containment facility is and how few of them there are in the world?"

Dr. FAUCI. "Yes. A Level 4 facility is the highest level facility for a microbe. There are very few of them in this country. There is one if Fort Dietrich, there is one at the CDC in Atlanta, there is one operational in Texas and one planned in Texas. We are planning two additional ones right now, and those are the two I mentioned. The one that we are going to be partnering with the Department of Defense up at Fort Dietrich to make that a much more enhanced biodefense arena, and one that we are going to be putting in Rocky Mountain Laboratory, which is an NIH facility in Hamilton, Montana."

This is clearly a violation of CEQ 1502.2 (g): "Environmental impact statements shall serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made."

Public handouts provided by NIH at scoping meetings in Hamilton, MT stated that the proposed project "will be" constructed.

This attempt at providing a foregone conclusion clearly had the effect of making many of the public believe that the decision had been made – inhibiting the public input process required by NEPA. The attempt to intimidate the local public and make them feel that there was no alternative to having the proposed project implemented is poor public process and a violation of the spirit and letter of NEPA.

3.2 Construction began for proposed alternative, and irrevocably committed resources.

62-42 • Construction of a "construction office" onsite. (Comments by Will Daellenbach, Project director for the overall RML facilities upgrade, at the 6/4/03 Citizen's Liaison Group (CLG) meeting. The minutes of that meeting state: "Will also wanted the group to know that the majority of the construction performed up to date has been done by local contractors/subcontractors.") This irrevocably commits government funds for construction that will not be needed if the no action alternative is selected. This illegal

Comment	Response
62-42	Please see Section 1.7.5 where comments that construction had already begun were addressed.

62-43 • Hiring of Higgins Development Partners to manage the project to the extent that any government funds are obligated for construction.

62-44 • Hiring of Skanska as a general contractor for the project. (CLG meeting minutes 6/4/03) This appears to irrevocably commit government funds for startup costs and/or for termination costs if the project does not go forward. The contractor has no role in preparing the information to support any analysis or information provided in the DEIS (See DEIS List of Preparers). If the contract allows obligation of government funds prior to the Record of Decision, it should be terminated immediately.

3.3 Purchase of land by BSL-4 expansion project managers Higgins Development Partners adjacent to RML for resale to RML.

[Hamilton City Council member] "Williamson expressed some concerns regarding property purchased by Higgins Development. Dr. Bloom explained that they had a problem on the south border, with residences close to the perimeter. There was an opportunity to acquire six lots to the north (on 6th Street). The developer overseeing the lab construction purchased the land with the idea that the lab would eventually acquire the property. The goal was to eliminate an unsafe area. They originally had hoped to enclose the lots within the campus area to use for parking, laying down pipes, etc. That was the original intent. However, Higgins Development did not fully research the property, and there may be zoning issues. The need is no longer critical at this time, and the lab still hopes to acquire the property." (Hamilton City Council Minutes 4/15/2003)

62-45 We hereby request under the Freedom of Information Act and under the disclosure requirements of NEPA that ALL correspondence, emails, and phone records related to purchase of these lots by Higgins. We specifically ask which government employees or contractors hired to help prepare the DEIS initiated, suggested or had prior knowledge of the above-mentioned purchase.

62-46 3.4 Apparent Violation of Antitrust, Federal Procurement, and Conflict of Interest Laws.

In addition to the predetermination issues with the purchase, the purchase also appears to violate Federal Procurement Laws and the Antitrust act. NIH's developer had inside information unavailable to the public or other businesses. NIH's developer had knowledge that these lands had a potential use for the laboratory expansion. In fact, it appears that it was plans they developed that created the need. NIH's developer used this inside knowledge to attempt to make a profit at the expense of the taxpayer. NIH's developer used this inside knowledge to acquire an unfair and illegal advantage over other businesses and individuals doing business with the government.

We request that the purchase of the above-mentioned lots by NIH's contractor be fully investigated, the results be disclosed to the public, and any violations of law or regulation be rectified.

Comment	Response
62-43	Please see section 1.7.5 where comments that construction had already begun were addressed.
62-44	Please see section 1.7.5 where comments on expenditures were addressed.
62-45	Please see response to comment 58-1. The requirements for submitting a request for DHHS records under the Freedom of Information Act are set forth in 45 CFR Part 5.
62-46	When the property was available for purchase, anyone could have bought it. It is not a conflict of interest, unfair, or illegal for a party interested in purchasing property to have an idea how the property may be used by themselves. No government funds have been used in the purchase of lots in Hamilton for the purpose of the Integrated Research Facility and the purchase was not made at the request or direction of the NIH or any NIH official. Higgins Development Partners purchased this land when it became available in the event that RML wanted to use it in the future.

Comments on the Supplemental Draft Environmental Impact Statement, Integrated Research Facility,RML, February 2004 Friends of the Bitterroot – Women's Voices for the Earth – Coalition for a Safe Lab

4. Scope is too limited.

62-47 NIH has arbitrarily limited the scope of the DEIS. This is an obvious and transparent attempt to limit the scope to a location and budget that was predetermined to avoid considering a reasonable range of alternatives, and disclosing the rational for the choice of location or budget tradeoffs.

The scope of the EIS should be to develop a regional center of excellence within the Northwestern portion of the United States for the study of emerging Category A, B, and C biological pathogens and respond to biological terrorism.

The DEIS itself shows that the BSL-4 need is part of a national initiative to respond to terrorism and the nationwide threat of emerging diseases.

The NIH and RML have published numerous pronouncements that the expansion to RML to include an expanded integrated laboratory (including a BSL-4 lab) is part of a national initiative. A sample of these statements by NIH officials is contained in Appendix A.

4.1 The DEIS itself shows that the scope of this decision includes locations throughout the western United States.

NIH has a nationwide infrastructure in which to carry out its expanded research program.

> "NIH is organized into several divisions, with RML part of NIH's Division of Intramural Research. NIH is one of 27 Institutes or Centers of NIH." (DEIS 4-1)
>
> "NIH has developed a research agenda for "Category A" agents (USDHHS 2002b)." (DEIS 1-4)
>
> "This research agenda acknowledges that certain research on potentially deadly disease agents must be conducted in appropriate containment facilities."

The need is a national need that is not specific to RML.

> "As a result, President Bush tasked the National Institute of Allergy and Infectious Diseases (NIAID) to increase its research into the development of safe and effective countermeasures to protect the public against the threat of biological agents that might be used for bioterrorism. These goals are commensurate with past and current research by NIAID." (DEIS S-1)

The DEIS recognizes that the proposed alternative is designed to meet this national need.

> "As part of the expanded research program, NIH's Proposed Action to construct an Integrated Research Facility… at the RML." (DEIS S-1)

Comment	Response
62-47	As explained in the EIS, the scope of the project is established by the purpose and need, which itself is established by agency authority. The purpose and need for the project is at the agency's discretion.

4.2 The NIH and RML have issued several reports and public pronouncements that show that the scope of the decision includes locations throughout the western United States.

See samples from the public record in Appendix A.

4.3 The budgetary constraint is arbitrarily imposed in the defined scope of the DEIS.

62-48 This is an obvious and transparent attempt to avoid considering rational for the choice of location or budget tradeoffs. The overall NIH budget for BSL construction is over $500 million. (PALMORE 2002)

4.4 The DEIS fails to comply with the NEPA/CEQ's regulations regarding the scoping process, (40 CFR 1501.7; 1508.25).

62-49 The DEIS apparently refused to consider public input suggesting reasonable alternatives, and unduly limited the Proposed Project's "Scope" to build it at the RML in Hamilton, Montana (DEIS S-2, 2-1, 1-6, 2-9, A-10). This appears to be in significant conflict with the regulations.

1501.7 SCOPING.

"There shall be an early and open process for determining the scope of issues to be addressed and for identifying the significant issues related to a proposed action. This process shall be termed scoping.

As soon as practicable after its decision to prepare an environmental impact statement and before the scoping process the lead agency shall publish a notice of intent (1508.22) in the FEDERAL REGISTER except as provided in 1507.3(e). (a) As part of the scoping process the lead agency shall: .... (2) Determine the scope (1508.25) and the significant issues to be analyzed in depth in the environmental impact statement. (3) Identify and eliminate from detailed study the issues which are not significant or which have been covered by prior environmental review (1506.3), narrowing the discussion of these issues in the statement to a brief presentation of why they will not have a significant effect on the human environment or providing a reference to their coverage elsewhere. .... (c) An agency shall revise the determinations made under paragraphs (a) and (b) of this section if substantial changes are made later in the proposed action, or if significant new circumstances or information arise which bear on the proposal or its impacts."

1508.25 SCOPE.

"Scope consists of the range of actions, alternatives, and impacts to be considered in an environmental impact statement. The scope of an individual statement may depend on its relationship to other statements (1502.20 and 1508.28). To

Comment	Response
62-48	Please see response to comments 62-7 and 62-47.
62-49	Please see response to comment 62-47, and Sections 1.7 and 1.7.1 where comments on the alternatives were addressed.

determine the scope of environmental impact statements, agencies shall consider 3 types of actions, 3 types of alternatives, and 3 types of impacts. They include: (a) Actions (other than unconnected single actions) which may be: (1) Connected actions, which means they are closely related and therefore should be discussed in the same impact statement. Actions are connected if they: (i) Automatically trigger other actions which may require environmental impact statements. (ii) Cannot or will not proceed unless other actions are taken previously or simultaneously. (iii) Are interdependent parts of a larger action and depend on the larger action for their justification. (2) Cumulative actions, which when viewed with other proposed actions have cumulatively significant impacts and should therefore be discussed in the same impact statement. (3) Similar actions, which when viewed with other reasonably foreseeable or proposed agency actions, have similarities that provide a basis for evaluating their environmental consequences together, such as common timing or geography. An agency may wish to analyze these actions in the same impact statement. It should do so when the best way to assess adequately the combined impacts of similar actions or reasonable alternatives to such actions is to treat them in a single impact statement. ... (b) Alternatives, which include: (1) No action alternative. (2) Other reasonable courses of actions. (3) Mitigation measures (not in the proposed action).

(c) Impacts, which may be: (1) Direct; (2) Indirect; (3) cumulative."

It appears that NIH's mind was made up from the beginning - that there was only one "Action Alternative" this DEIS would analyze. The issue was appropriately and timely raised by the public, there is an already built BSL-4 available, another is being planned or built (Texas), and there appears there may other BSL-4 proposals in other States.

The DEIS arbitrarily and capriciously restricted the "scope" of it's analysis and range of alternatives.